

BECTON, DICKINSON AND COMPANY,
GENEOHM SCIENCES CANADA, INC.,
and HANDYLAB, INC.,

[illegible]

C.A. No. 19-1126-LPS

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MEMORANDUM OPINION

May 10, 2021
Wilmington, Delaware



STARK, U.S. District Judge:

On June 18, 2019, Plaintiffs Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc., and HandyLab, Inc. (collectively, “Plaintiffs”) filed a patent infringement suit against NeuMoDx Molecular, Inc. (D.I. 1) On February 18, 2021, the parties stipulated to the joinder of Qiagen North American Holdings, Inc. and Qiagen GmbH (together, with NeuMoDx Molecular, Inc., “Defendants”). (D.I. 159)

The suit alleges infringement of U.S. Patent Nos. 8,273,308 (the “’308 patent”), 8,703,069 (the “’069 patent”), 7,998,708 (the “’708 patent”), 8,323,900 (the “’900 patent”), 8,415,103 (the “’103 patent”), 8,709,787 (the “’787 patent”), 10,494,663 (the “’663 patent”), 10,364,456 (the “’456 patent”), 10,443,088 (the “’088 patent”), 10,604,788 (the “’788 patent”), 10,625,261 (the “’261 patent”), 10,625,262 (the “’262 patent”), and 10,632,466 (the “’466 patent”). (D.I. 54) The 13 patents-in-suit relate to technologies used in commercial diagnostic systems for microfluidic processing of nucleic acids and detection of bacterial and viral pathogens. (D.I. 146 at 1)

Presently before the Court is the issue of claim construction. The parties submitted technology tutorials (*see* D.I. 128, 129), objections to the tutorials (D.I. 140, 141), a joint claim construction brief (D.I. 146), and exhibits (D.I. 146-1, 146-2, 146-3, 146-4, 146-5, 146-6, 146-7, 146-8, 146-9, 146-10). The Court held a claim construction hearing on February 23, 2021, at which both sides presented oral argument. (D.I. 177) (“Tr.”) Subsequently, the parties submitted supplemental letter briefing. (D.I. 179, 184)

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the

claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal citation and quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent “specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent.” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one

party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316.

It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (alteration in original) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370. The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

“In some cases . . . the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. “Extrinsic evidence consists of all evidence external to the patent and prosecution

history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted).

II. CONSTRUCTION OF DISPUTED TERMS

A. “multi-lane microfluidic cartridge” / “multi-lane microfluidic cartridges”¹

Plaintiffs “A microfluidic cartridge comprising a plurality of sample lanes with separate sample inlets and microfluidic networks” “Microfluidic cartridges comprising a plurality of sample lanes with separate sample inlets and microfluidic networks”
Defendants Plain and ordinary meaning. No construction is necessary.
Court “A microfluidic cartridge comprising a plurality of sample lanes with separate sample inlets and microfluidic networks” “Microfluidic cartridges comprising a plurality of sample lanes with separate sample inlets and microfluidic networks”

Construction is necessary because the parties have a genuine dispute over claim scope and that dispute appears to be material. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). The parties’ dispute centers on the meaning of “lane” within the broader term “multi-lane microfluidic cartridge.” Plaintiffs argue that the term “lane” requires a separate sample inlet and microfluidic network, adding that this construction reflects the patented invention’s innovation in speeding up processing time by enabling separate lanes in the cartridge to process multiple samples “at the same time or independently.” (Tr. at 5; *see also* D.I. 146 at 6)

For support, Plaintiffs point to the Patent Trial and Appeal Board’s (“PTAB”) adoption of their proposed construction in two final written decisions issued in IPRs of the ’708 and ’900 patents.² (D.I. 146 at 5-6) The PTAB was persuaded that the language in the patents’ common

¹ This term appears in claims 1-33 of the ’708 patent, claims 1-22 of the ’900 patent, and claims 23-30 of the ’466 patent. The ’708 and ’900 patents share a common specification.

² Plaintiffs argue that the Court should adopt the PTAB’s construction as a matter of collateral estoppel. (D.I. 146 at 5) The Court declines to do so for two reasons. First, while courts have

specification requiring that “[a] sample lane comprise[] at least a sample inlet, and a microfluidic network” described the structure of a sample lane. *See Qiagen N. Am. Holdings v. HandyLab, Inc.*, No. IPR 2019-00490, Paper 51 at 12 (P.T.A.B. July 14, 2020) (“’900 patent decision”) (citing ’900 patent at 13:4-9). The PTAB also noted the specification’s teaching that each lane is associated with a *separate* sample inlet to prevent contamination. *See id.* at 13 (citing ’900 patent at 15:4-10). The Court agrees with the PTAB that the specification provides support for Plaintiffs’ proposed construction.

Further, although the ’466 patent was not subject to IPR, its specification contains similar language describing the sample lane’s structure and associating each lane with a separate sample inlet. *See, e.g.*, ’466 patent at 35:56-57 (“A lane comprises at least a sample inlet, and a microfluidic component.”); *id.* at 37:7-8 (“[S]ample inlets of adjacent lanes are reasonably spaced apart from one another to prevent any contamination.”). The Court will adopt the same construction for the same term as it appears in the ’466 patent.

Defendants incorporate the claim construction arguments they made during the IPRs. (*See* D.I. 146 at 7; Tr. at 12) Like the PTAB, this Court is not persuaded by Defendants’ argument that “lane” and “sample lane” refer to separate structures. (*See* Tr. at 10; ’900 patent decision at 13-14 (citing, *e.g.*, ’900 patent at 12:66-13:3)) As the PTAB noted, the terms are used interchangeably in the specification, and Defendants provide no evidence to suggest the two terms differ. *See* ’900 patent decision at 13-14. The Court finds similarly unavailing

held broadly that collateral estoppel applies in the administrative context, *see, e.g., B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148-49, 160 (2015); *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018), this Court is unaware of any binding caselaw holding that a PTAB claim construction ruling has preclusive effect in district court prior to its review by the Federal Circuit. Plaintiffs concede that they have not found a case in which a court applied collateral estoppel in this context. (Tr. at 7) Second, although the ’708 and ’900 patents were the subject of IPRs, the ’466 patent was not. (*See* D.I. 146 at 5)

Defendants’ argument that “lane” may comprise a number of additional elements beyond those proposed by Plaintiffs. (*See* Tr. at 10) For this contention, Defendants largely rely on language in the specification that begins, “[i]n various embodiments, a sample lane can include . . . ,” which suggests that these additional elements are optional and should **not** be read into the claims as limitations. (*See id.* at 13; *Liebel-Flarsheim*, 358 F.3d at 906) Finally, the Court finds no basis to replace the claim term “lane” with “channel,” especially since the specification refers to “channels” and “lanes” as distinct structures. *See* ’900 patent decision at 14-15 (citing, e.g., ’900 patent at 18:59-61).

B. Claim terms reciting the word “independently” or “independent”³

Term	Plaintiffs	Defendants	Court
“each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples” ⁴ “the plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another” ⁵ “reaction chambers are configured to permit thermal cycling of the plurality of	Plain and ordinary meaning. No construction is necessary. Alternatively, “encompassing parallel, separate, simultaneous, or successive processing.”	Thermal cycling of one sample is not dependent on thermal cycling of another sample.	“Capable of parallel, separate, simultaneous, or successive processing.”

³ This term appears in claim 33 of the ’708 patent, claims 20-22 of the ’900 patent, claims 9 and 12 of the ’787 patent, and claims 1-15 of the ’103 patent. The ’708 and ’900 patents share a common specification.

⁴ This term appears in claim 33 of the ’708 patent and claims 20-22 of the ’900 patent.

⁵ This term appears in claim 9 of the ’787 patent.

samples independently of one another” ⁶			
“amplify one or more polynucleotides independently of the other lanes” ⁷ “carrying out amplification independently on a plurality of polynucleotide-containing samples” ⁸ “amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample” ⁹ “amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers” ¹⁰	Plain and ordinary meaning. No construction is necessary. Alternatively, “encompassing parallel, separate, simultaneous, or successive processing.”	Amplification of one sample is not dependent on amplification of another sample.	“Capable of parallel, separate, simultaneous, or successive processing.”

Simple, non-technical terms often do not require construction. *See Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001); *see also Funai Elec. Co. v. Daewoo Elecs. Corp.*, 616 F.3d 1357, 1366 (Fed. Cir. 2010) (“The criterion is whether the explanation aids the court and the jury in understanding the term as it is used in the claimed invention.”). Here, however, the Court concludes that it must construe the term “independent/ly” because the parties do not agree on its meaning and their dispute appears to be material. *See O2 Micro*, 521 F.3d at 1361

⁶ This term appears in claims 3 and 15 of the ’103 patent.

⁷ This term appears in claim 12 of the ’787 patent.

⁸ This term appears in claims 1-15 of the ’103 patent.

⁹ This term appears in claims 1-14 of the ’103 patent.

¹⁰ This term appears in claim 15 of the ’103 patent.

("[Sometimes] the 'ordinary' meaning of a term does not resolve the parties' dispute, and claim construction requires the court to determine what claim scope is appropriate in the context of the patents-in-suit.").

The parties agree that, at a minimum, "independent/ly" encompasses a capability to perform "parallel, separate, simultaneous, or successive" processing. (*See* D.I. 179 at 1; D.I. 184 at 1-2) Plaintiffs argue that the term should receive the "full breadth of its plain and ordinary meaning." (D.I. 179 at 1) Defendants, on the other hand, believe construction is necessary to aid the jury in understanding the term's use across various contexts. (*See* D.I. 146 at 18, 20) Defendants ask the Court to read into the disputed term a limitation that "thermal cycling or amplification of one sample is **not dependent on** another sample." (*Id.* at 19 (emphasis added); *see also* D.I. 184 at 1) Relatedly, they assert that "independent" means **fully** independent and requires every embodiment of every claim at issue to have the ability to perform **both** successive and simultaneous processing. (*See* Tr. at 28, 34)

The Court is not persuaded by Defendants' proposed narrowing. Defendants have pointed to no claim language, lexicography, disclaimer, or disavowal that would suggest to a person of ordinary skill in the art ("POSA") that the term should be construed as "not dependent on" or "fully independent." *See Phillips*, 415 F.3d at 1316. Instead, Defendants rely primarily on particular embodiments to argue the claims should be so limited. (*See, e.g.*, D.I. 184 at 2) For example, Defendants point to embodiments in which each lane in the microfluidic cartridge has its own optical detector. (*See id.*) (citing '900 patent at 36:19-40) Such a configuration would allow for both simultaneous **and** successive processing, and thus, in Defendants' view, would fall squarely within the claim scope. (*See id.*) By contrast, Defendants assert that an embodiment with just **one** optical detector that scans across the lanes would not be within the

scope of the claims because it would be incapable of simultaneous processing; as such, Defendants argue, the patents disclose only optical detectors with the same number of detectors as lanes. (*See id.*; Tr. at 31-32)

Plaintiffs, by contrast, point to an embodiment in which “a single detector . . . can scan across all of the multiple cartridges.” (Tr. at 20) (citing ’708 patent at 8:4-14) In addition, Plaintiffs note that dependent claim 14 of the ’103 patent references a “scanning read head,” and that the ’103 patent’s specification contemplates “a single PCR reader, with a scanning read-head, capable of reading up to 4 different colors from each of the PCR lanes.” (*See* D.I. 179 at 2; Tr. at 20-21 (citing ’103 patent at 45:45-56)) Plaintiffs contend that, in both instances in which there may be fewer detectors than lanes, some coordination is necessary and, thus, full independence is not required. (*See* Tr. at 20-22, 41; *see also* D.I. 179 at 2 (citing ’900 patent at 36:25-40))

The Court agrees with Plaintiffs that the patent claims do not foreclose the possibility of an embodiment with a single detector or a different number of detectors than lanes. (*See* D.I. 179 at 2) As a threshold matter, it is not necessarily true that an embodiment with a single detector would **not** be capable of simultaneous processing. (*See* Tr. at 40) The common specification for the ’708 and ’900 patents, for example, describes a single detector embodiment “configured to permit . . . simultaneous control.” (*See id.* at 20) (citing ’708 patent at 8:4-14) Further, Defendants concede that “simultaneous” covers a scenario in which two processes **begin** at different times and there is partial overlap during which the two processes are occurring at the same time. (*Id.* at 36) The Court does not have a record establishing that a single detector embodiment is incapable of performing such a task. (*See id.* at 40)

The Court, however, need not decide today whether a single detector embodiment is capable of simultaneous processing, as the claim language does not require the ability to perform **both** simultaneous and successive processing. The Court declines to adopt Defendants' narrow construction. *See Liebel-Flarsheim*, 358 F.3d at 906.

Instead, the Court's construction uses descriptors that will be helpful by informing the jury of the term's meaning within the patent. (*See* D.I. 179 at 1) As noted, the Court's construction is supported by the specifications. *See, e.g.*, '708 patent at 13:55-57 (describing "microfluidic cartridge 100 containing twelve independent sample lanes 101 capable of **simultaneous or successive** processing") (emphasis added); '787 patent at 23:20-31 (describing "microfluidic cartridge containing multiple sample lanes capable of processing samples in **parallel**" and configured to "detect and analyze the products of the PCR amplification in each of the lanes **separately**") (emphasis added).

C. "first module"¹¹

Plaintiffs

Plain and ordinary meaning. No construction is necessary. Alternatively, "an assembly of components configured to extract nucleic acids from the plurality of nucleic acid-containing samples."

Defendants

"An assembly of components at the first location configured to extract nucleic acids from the plurality of nucleic acid containing samples, the components including a plurality of process chambers at the first location, a magnetic separator operating on the process chambers and a heating assembly operating on the process chambers." Alternatively, "an assembly of components at a first location configured to extract nucleic acids from the plurality of nucleic acid containing samples."

Court

"An assembly of components configured to extract nucleic acids from the plurality of nucleic acid-containing samples."

¹¹ This term appears in claims 1-30 of the '261 patent, claims 1-24 of the '262 patent, and claims 1-30 of the '466 patent. These three patents share a common specification.

The parties' dispute over whether a "first module" requires a location distinct from that of the "second module" must be resolved by claim construction. (*See* D.I. 179 at 4; D.I. 184 at 3; *see also O2 Micro*, 521 F.3d at 1361) The specification defines "module" as "an assembly of components, each of which may have separate, distinct and/or independent functions, but which are configured to operate together to produce a desired result or results." '261 patent at 7:15-19. Both parties agree that this language constitutes express lexicography defining module. (*See* Tr. at 94, 98) The parties further agree that there must be two modules, and that these modules have separate functions as provided by the claims. (*See id.* at 93-94, 97, 102, 110)

Defendants seek to narrow the terms further by imposing a requirement that the modules be in distinct locations. (*See* D.I. 184 at 3) The Court, however, is not persuaded that a POSA would understand that distinct locations are required.

Defendants rely heavily on several embodiments in which the two modules are in separate locations. (*See, e.g.,* Tr. at 100-04, 107) Specification embodiments should not, however, be read to narrow claim scope in the absence of a clear intention to do so. *See Liebel-Flarsheim*, 358 F.3d at 906. The Court finds no such intent here, especially given that – as Plaintiffs note – some of the embodiments are expressly exemplary and "not intended to be limiting" with respect to location. (Tr. at 90; *see also* D.I. 179 at 4 (citing '261 patent at 7:32-34))

Defendants argue that a construction without a location requirement would allow for complete overlap in location, collapsing the modules and reading out the "first" and "second" limitations. (*See* D.I. 184 at 3; Tr. at 98) But Plaintiffs do not seem to view complete overlap as practicing the claims, and there is nothing in the claim language or specification that justifies eliminating all overlap in location. (*See* Tr. at 111-12) The recitation of "first" and "second" in

the claims does not mandate that the modules have distinct locations. (*See id.* at 92-93; *see also Linear Tech. Corp. v. Int’l Trade Comm’n*, 566 F.3d 1049, 1055 (Fed. Cir. 2009) (declining to construe “second circuit” and “third circuit” as entirely distinct because “there is nothing in the claim language or specification that supports narrowly construing the terms to require a specific structural requirement or entirely distinct ‘second’ and ‘third’ circuits”)))

D. “second module”¹²

<p>Plaintiffs</p> <p>Plain and ordinary meaning. No construction is necessary. Alternatively, “an assembly of components configured to amplify the nucleic acids extracted from the plurality of nucleic acid-containing samples.”</p>
<p>Defendants</p> <p>“An assembly of components at the second location configured to amplify the nucleic acid extracted from the plurality of nucleic acid containing samples, the components including a bay receiving a microfluidic cartridge or plurality of receptacles at the second location.” Alternatively, “an assembly of components at a second location configured to amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples.”</p>
<p>Court</p> <p>“An assembly of components configured to amplify the nucleic acids extracted from the plurality of nucleic acid-containing samples.”</p>

The dispute and its resolution are the same as for the previous term.

¹² This term appears in claims 1-30 of the ’261 patent, claims 1-24 of the ’262 patent, and claims 1-30 of the ’466 patent. These three patents share a common specification.

E. “valve” / “set of microfluidic valves”¹³

Plaintiffs

Plain and ordinary meaning. No construction is necessary. Alternatively, “a component that can control, modify, or regulate the flow of fluid that can pass through it or through a channel.”

Defendants

The first and second valves are components in communication with a channel with a normally open state allowing material to pass along a channel from a position on one side of the component to the other side.

The first and second sets of microfluidic valves are components in communication with a channel with a normally open state allowing material to pass along a channel from a position on one side of the component to the other side.

Court

A valve is “a component that can control, modify, or regulate the flow of fluid that can pass through it or through a channel.”

Construction is necessary because the parties have a genuine dispute over the scope of the term “valve” which appears to be material. *See O2 Micro*, 521 F.3d at 1361. Defendants propose that the valves be “normally open,” which has a specific meaning in the art. (*See* D.I. 146 at 76) Plaintiffs argue that “valve” has a broad meaning in the field of microfluidics and within the patents at issue. (*Id.* at 62; D.I. 179 at 2)

As a threshold matter, the parties disagree as to which “valves” are at issue. (*See* D.I. 146 at 68, 73; Tr. at 75-77) The Court agrees with Defendants that the dispute centers on the valves immediately surrounding the DNA manipulation zone, and not all valves in the system. (*See* D.I. 146 at 68) However, even agreeing with Defendants on this point, the Court is not persuaded that such valves must be normally open.

While the focus of the claim term in dispute here is the valves surrounding the DNA manipulation zone, the Court adopts Plaintiffs’ alternative construction proposed in their

¹³ This term appears in claims 1-25 of the ’308 patent, claims 1-10 of the ’069 patent, and claims 1-22 of the ’787 patent. The ’308 and ’069 patents share a common specification.

supplemental brief (D.I. 179 at 2), which applies not only to those valves but also to the valves disclosed more broadly throughout the patents.

Defendants assert theories of lexicography and disavowal in support of their proposed narrow construction of “valve.” (See D.I. 184 at 2-3) As the Federal Circuit has explained, there is a “heavy presumption that claim terms carry their full ordinary and customary meaning unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution.” *Omega Eng’g, Inc. v. RaytekCorp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (internal citations and quotation marks omitted).

As to the ’787 patent, Defendants argue that the patentee narrowed the term “valve” with express lexicography. (D.I. 184 at 2) According to Defendants, the specification of that patent defines valve with the following language, which appears in the first sentence under a header entitled “Valves”: “[a] valve (sometimes referred to herein as a microvalve) is a component in communication with a channel, such that the valve has a normally open state.”¹⁴ (D.I. 146 at 68) (citing ’787 patent at 12:35-46) Plaintiffs respond by observing that this section of the specification is prefaced by a caveat that the descriptions to follow refer to certain embodiments. (See *id.* at 64 (citing ’787 patent at 3:27-31); Tr. at 50) Plaintiffs also point out that elsewhere the patentees indicated an intent to be their own lexicographers through a different language convention. (See Tr. at 50) (citing ’787 patent at 4:50-65 (“[b]y **cartridge** is meant . . .” and “[b]y **microfluidic** . . . is meant . . .”) (emphasis added))

¹⁴ Defendants also note that this same definition is repeated in ten other patents-in-suit, and they urge the Court to apply a consistent definition across the patents. (See D.I. 146 at 68; Tr. at 67-68) To the Court, however, it is more notable that the definition on which Defendants rely is *not* present in two of the patents-in-suit, the ’308 and ’069 patents. This suggests the omission in these patents was intentional.

The Court agrees with Plaintiffs that the '787 patent does not set forth clear lexicography narrowing the term “valve” as used in the claim term being construed. A noun followed by “is” or “are” does not always “unambiguously signify that the description provided is definitional.” *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007). The Federal Circuit has contrasted such general statements with terms it *has* held to be limiting, such as “the present invention includes . . .” or “[a certain term] means . . .” See *Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1347 (Fed. Cir. 2020); *Abbott*, 473 F.3d at 1210. Here, given the general nature of the language Defendants contend is “definitional” and its placement within the patent, the Court concludes that it does not constitute clear lexicography defining the term “valve” as used throughout the patent.¹⁵

Second, as to the '308 patent,¹⁶ Defendants point to the prosecution history, arguing that Plaintiffs disavowed “normally closed” valves as well as those merely configured to close when they amended the claim to remove the language indicating that the valves were “configured to close or open the zone.” (D.I. 146 at 71; D.I. 89 Ex. 14 at BD_NMDX_0002795-800) Plaintiffs explain, however, that the amendment responded to the patent examiner’s note that the level of detail was deficient, not that the claims lacked support in the specification. (See D.I. 146 at 76 n.38; Tr. at 52-53) Further, there was no clear disparagement of normally closed valves, and the patentee clarified that amendments should not be interpreted as “disclaimers or disavowals of any subject matter supported by the present application.” (D.I. 146 at 76-77; see also Tr. at 73)

¹⁵ Even if the Court reached the opposite conclusion, this rationale would apply only to the '787 patent, as the language cited by Defendants does not appear in the specification common to the '308 and '069 patents.

¹⁶ The '308 patent is a parent of the '069 patent. To Defendants, then, their arguments regarding disavowal during prosecution apply equally to the '069 patent. (See Tr. at 63)

Taken together, the evidence fails to evince a clear and unmistakable disavowal of claim scope. *See Omega*, 334 F.3d at 1325-26 (“[T]he alleged disavowing actions or statements made during prosecution [must] be both clear and unmistakable.”).

The Court’s conclusions are also supported by language in both the patents’ dependent claims and specifications referring to valves more broadly. *See, e.g.*, ’308 patent at 16:42-48 (expressly requiring “opening the first valve” before taking next step, suggesting that valve is **not** “normally open”); *id.* at 6:31-35 (stating that valves “may be of any type suitable for use in a microfluidic device, . . . [and] may be reversible between the open and closed states”).

Finally, the parties argued at length during the *Markman* hearing (*see* Tr. at 70-73, 78-86) about whether a normally closed valve would be capable of satisfying the limitations throughout the patent requiring that the valve be “closed.” *See, e.g.*, ’308 patent at 15:55-16:16, 17:13-18:20; ’069 patent at 16:2-17. Plaintiffs contend that nothing prevents a normally closed valve from being opened and then closed again. (*See* Tr. at 71-72) With equal confidence, Defendants represent that a POSA would understand it is technically **impossible** for a valve to be normally closed, then opened, then closed again. (*See id.* at 82) On the record presently before it, the Court is unable to find that a POSA would reject the idea that a normally closed valve would be capable of opening and then closing.¹⁷

¹⁷ The Court reaches the same conclusion with respect to whether thermally responsive substance (“TRS”) valves must be normally open, as Defendants suggest. (*See* D.I. 146 at 69; Tr. at 58) Plaintiffs dispute this contention, arguing that TRS valves can indeed be normally closed. (D.I. 146 at 75 n.37; Tr. at 51-52) Further, Plaintiffs refute Defendants’ contention that all valves surrounding the DNA manipulation zone **must** be TRS valves. (*See* D.I. 146 at 75 (citing ’787 patent at 12:45-48) (“For example, in one embodiment, a valve can include a mass of a [TRS].”); Tr. at 58, 73) At this stage, the Court is not persuaded that (1) all valves at issue are TRS valves and (2) all TRS valves must be normally open.

F. “programmed to close the first and second valves” / “closing the first valve and the second valve”¹⁸

Plaintiffs
Plain and ordinary meaning. No construction is necessary.
Defendants
The controller is programmed to close first and second valves that start in an open position to prevent gas and liquid from flowing into or out of the DNA manipulation zone.
The first and second valves that start in an open position are closed to prevent gas and liquid from flowing into or out of the DNA manipulation zone.
Court
No construction is necessary.

In response to Plaintiffs’ objections, Defendants modified their proposed constructions such that they now do little more than parrot the claim language, adding only that the valves must “start in an open position.” (See D.I. 146 at 81-82) Plaintiffs argue this construction is unnecessary “because the jury will understand that to close a component, logically the component was *previously* open.” (*Id.* at 83) (emphasis added) But Defendants confirmed that their proposed construction for this term aims again to import the limitation that the “valves must close from a normally open state.” (*Id.* at 83-84) Having rejected Defendants’ proposal that the valves must be “normally open,” the Court likewise rejects the limitation that the valves must “start in an open position.” The Court’s construction of “valve” resolves the remaining dispute as to this term and, thus, construction is not required.

¹⁸ This term appears in claims 1-25 of the ’308 patent and claims 1-10 of the ’069 patent. These two patents share a common specification.

G. “process chambers”¹⁹

Plaintiffs Plain and ordinary meaning. No construction is necessary. Alternatively, “a component, for a process, having an interior space for holding fluid.”
Defendants “Open tubes having an interior space for holding fluid.” Alternatively, “an open tube component, for a process, having an interior space for holding fluid.”
Court “A component, for a process, having an interior space for holding fluid.”

Plaintiffs have not demonstrated that the term “process chambers” has a plain and ordinary meaning in the art. *See Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1164 (Fed. Cir. 2004).

The parties agree that “process chambers” have an “interior space for holding fluid,” but they dispute whether they must be open tubes. (*See* D.I. 179 at 4; D.I. 184 at 4) The claim language does not reference the term “tubes” or provide much guidance as to the meaning of “process chambers.” Defendants point to embodiments in the specification they contend refer to “process tubes” and “process chambers” interchangeably. *See, e.g.*, ’261 patent at 14:39-45; *id.* at 63:35-56, 29:50-52, 30:32-37 (referring to same component 1402 as both “process chamber” and “process tube”). Plaintiffs counter that while a tube is a chamber, a chamber is not necessarily a tube. (Tr. at 122) That certain tubes are described as chambers is, thus, irrelevant. (*See* D.I. 179 at 4) Further, Plaintiffs point to instances in which the specification and claims use different language when referring to “chambers” and “tubes,” suggesting that the two are distinct components. (*See* D.I. 146 at 85) (citing, *e.g.*, ’261 patent at 19:20-23, which refers to “various tubes and chambers”) The summary of the invention, for example, distinguishes between

¹⁹ This term appears in claims 1-30 of the ’261 patent, claims 1-24 of the ’262 patent, and claims 1-30 of the ’466 patent. These three patents share a common specification.

“process chambers” and “process tubes.” (Tr. at 115; ’261 patent at 2:20-44, 3:16-23, 3:39-65, 4:17-23)

Defendants also point to a section toward the back of the patent entitled “Additional Advantages and Features of the Technology Herein,” in which the specification highlights the open tube structure of the process chambers as a key feature of the invention. (D.I. 146 at 86) (citing ’261 patent at 59:4-10) Defendants contend that this section defines “process chambers” “by implication.” (Tr. at 117) Plaintiffs dispute this assertion, arguing that this section instead provides “additional advantages that attend to some of the embodiments that have been previously described.” (*Id.* at 122) Further, “[a]dvantages described in the body of the specification, if not included in the claims, are not per se limitations to the claimed invention.” *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003) (internal citations omitted).

The parties’ arguments about prosecution history and claim differentiation do not alter the Court’s conclusions. The parent application claimed a holder comprising a “process chamber” with a dependent claim comprising a “process tube.”²⁰ (D.I. 146-8 Ex. Q at 154-55, 157) This does not provide much help in construing “process chambers.” Further, the differences between the independent claim and the dependent claim consist of more than just the “process tube” limitation appearing only in the dependent claim, weakening the support provided by claim differentiation. *See SunRace Roots*, 336 F.3d at 1303; D.I. 146 at 87.

In the end, the Court is persuaded by Plaintiffs that a POSA would not understand all “process chambers” are required to be open tubes. It would be improper here to import

²⁰ Even though the patent did not ultimately issue, the prosecution history is still relevant intrinsic evidence. *See Phillips*, 415 F.3d at 1317.

limitations from process chamber embodiments into the claims. *See Phillips*, 415 F.3d at 1323; *see also generally Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, 2014 WL 4352489, at *3 (E.D. Tex. Sept. 2, 2014) (“It is common for a specification to describe various advantages . . . of a claimed invention, but that does not mean that an accused product that does not embody each of those advantages . . . is thereby excluded from the patent’s coverage.”).

H. “process chamber”²¹

Plaintiffs
Plain and ordinary meaning. No construction is necessary. Alternatively, “an enclosed space where binding of polynucleotides occurs.”
Defendants
“A chamber for retaining binding particles where binding and release of polynucleotides occur.” Alternatively, “an enclosed space where binding and release of polynucleotides occur.”
Court
“An enclosed space where binding of polynucleotides occurs.”

As with “process chambers,” Plaintiffs have not demonstrated that “process chamber” has a plain and ordinary meaning in the art. *See Goldenberg*, 373 F.3d at 1164. The parties dispute whether the process chamber of the ’456 and ’088 patents need only **retain** polynucleotides, or if **release** of the polynucleotides must also occur there. (*See* D.I. 179 at 4-5; D.I. 184 at 4-5) The claim language makes clear that the first step (retention) occurs in a process chamber, but it leaves open the question whether the second step (release) must also occur there. *See* ’456 patent at 33:10-28; ’088 patent at 33:10-29.

Both parties agree that the specification teaches that the **binding particles** are configured to retain and release. (*See* D.I. 146 at 90-92; ’456 patent at 8:27-33) Plaintiffs, however,

²¹ This term appears in claims 1-13 of the ’456 patent and claims 1-21 of the ’088 patent. These two patents share a common specification.

contend that the binding particles' inclusion in the process chamber, at some point in time, does not necessarily require that both steps occur there. (D.I. 146 at 94)

Both parties point to descriptions in the specification of a "processing chamber" and a "processing region." Plaintiffs contend that these terms are used interchangeably, while Defendants assert that "processing region" is broader than "processing chamber." (*Id.* at 94-95; Tr. at 127-28, 135-36)

The specification teaches that "in some embodiments, the retention member can be removed from a **processing region** . . . and then moved to another location at which the polynucleotides are removed from the retention member." '456 patent at 16:23-29 (emphasis added). Plaintiffs portray this as conclusive evidence that release can occur at another location, but Defendants argue that this reference to a "processing region" should not inform the meaning of the narrower "processing chamber."

Defendants have failed to demonstrate that the intrinsic evidence requires reading the "release" step into the claimed process chamber. Defendants point to an embodiment in which a "processing chamber" includes the binding particles configured to retain and release the polynucleotides. (*See* D.I. 146 at 92) (citing '456 patent at 8:27-33) Nothing about this embodiment would tell a POSA that the "release" step **must** occur in the process chamber. The Court, thus, adopts the construction proposed by Plaintiffs in their supplemental brief. (*See* D.I. 179 at 5)

I. “lysing container”²²

Term	Plaintiffs	Defendants	Court
“The lysing container is located external to the microfluidic network.” ²³	Plain and ordinary meaning. No construction is necessary. Alternatively, “a container where lysis takes place.”	“A lysing chamber located external to the microfluidic network, but is still fluidically connected with the microfluidic network.”	“A container where lysis takes place.”
“The lysing container is outside of the microfluidic network.” ²⁴		“A lysing chamber located outside of the microfluidic network, but is still fluidically connected with the microfluidic network.”	
“A lysing container [is] located external to the substrate layers.” ²⁵		A lysing chamber located external to the substrate layers, but is still fluidically connected with the substrate layers.”	

Plaintiffs have not demonstrated that “lysing container” has a plain and ordinary meaning in the art. *See Goldenberg*, 373 F.3d at 1164. Still, however, the Court agrees with Plaintiffs that the plain language of the claims makes clear that the lysing container is “external to” or “outside of” the microfluidic network or substrate layers. (Tr. at 140-41) There is no need to import this requirement of other portions of the claim into the construction of “lysing container.” Additionally, Defendants’ proposed construction replaces the word “container” with “chamber,” for no persuasive reason, and Defendants later admitted they do not “feel strongly” about that substitution. (*Id.* at 147; *see also* D.I. 146 at 99 n.46) The Court will not adopt it.

²² This term appears in claims 1-49 of the ’663 patent and claims 1-55 of the ’788 patent. These two patents share a common specification.

²³ This term appears in claims 1-26 of the ’663 patent.

²⁴ This term appears in claims 27-49 of the ’663 patent.

²⁵ This term appears in claims 1-55 of the ’788 patent.

The remaining dispute is whether the lysing container must be fluidically connected with the microfluidic network. Plaintiffs clarified during the *Markman* hearing that they do not seek a construction that would **preclude** the lysing container from being fluidically connected with the microfluidic network; rather, in their view, the patent does not **require** such a connection. (Tr. at 144) As Plaintiffs note, this limitation is not present in the claim language. (D.I. 146 at 97-98)

As with many other claim terms, Defendants ask the Court to read in a limitation based on an embodiment. Here, the patents each have two embodiments. The first refers to “lysing” in the abstract, but not to a “lysing container.” (D.I. 146 at 99-100) Defendants note, by contrast, that the second and only embodiment that refers to a “lysing container” describes it as fluidically connected with the microfluidic network. (*Id.*) (citing, e.g., ’663 patent at 20:53-56) (explaining that material cannot pass between chambers internal to lysing container “without passing through at least a portion of” microfluidic network) Further, Defendants point to dependent claims – such as claim 20 of the ’663 patent, which “**assumes and requires**” their proposed microfluidic connection – as further support for their construction. (*Id.* at 100-01)

Defendants have shown no claim language, lexicography, disclaimer, or disavowal that would support the Court narrowing “lysis container” to only what is described in the second embodiment on which Defendants rely. *See generally Phillips*, 415 F.3d at 1316, 1323. It may be true that the dependent claims, like claim 20 of the ’663 patent, require a fluidic connection. *See* ’663 patent at 20:53-56. Such claims, however, are presumed to be narrower than the claims from which they depend and, here, do not dictate the meaning of “lysing container” in the independent claims. (*See* Tr. at 143; *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003))

Accordingly, the Court will adopt the construction proposed by Plaintiffs in their supplemental brief. (See D.I. 179 at 5)²⁶

J. “first processing region”²⁷

Plaintiffs
Plain and ordinary meaning. No construction is necessary. Alternatively, “a region or area that receives the lysate solution.”
Defendants
The first processing region is a region within the microfluidic network of the system that receives the lysate solution and the magnetic binding particles from the lysing container through a channel that connects the region with the lysing container.
Court
“A region that receives the lysate solution.”

The Court is not persuaded that “first processing region” has a plain and ordinary meaning in the art. *See Goldenberg*, 373 F.3d at 1164.

Plaintiffs note that the bulk of Defendants’ proposed construction – aside from the phrase, “through a channel that connects the region with the lysing container” – is already part of the claims through other claim language. (Tr. at 154-55; D.I. 146 at 106-07) The Court agrees. There is no need also to import this language into the term “first processing region.” (See D.I. 146 at 107-08)

The parties’ remaining dispute centers on Defendants’ proposed limitation that the first processing region be **connected with** the lysing container. As with its proposed construction of “lysing container,” Defendants ask the Court to read this limitation into the claims based on the

²⁶ While not dispositive, as Defendants correctly argue (*see* Tr. at 148-49), the Court agrees with Plaintiffs that there is specification support for Plaintiffs’ understanding of this claim term. (*See, e.g.*, D.I. 146 at 98) (citing ’663 patent at 3:25-29 and noting that lysis samples may be prepared “using microfluidic devices or on a larger scale” and that certain microfluidic devices may receive polynucleotides **after** lysis has occurred, implying that lysis can occur separate from the microfluidic network)

²⁷ This term appears in claims 1-49 of the ’663 patent and claims 1-55 of the ’788 patent. These two patents share a common specification.

specification's second embodiment. (*See id.* at 110; Tr. at 158) According to Defendants, “[a]s with the term ‘lysing container,’ there is no teaching in the specification that a first processing region may exist separate from and not connected to the lysing [container].” (D.I. 146 at 110)

However, as the Court already concluded in connection with the term “lysing container,” the claims do not require that the lysing container *must* be connected with the microfluidic network. For the same reasons already given with respect to “lysing container,” the Court is not persuaded here by Defendants’ arguments that it should narrow the claim term in the manner Defendants propose.

K. “second processing region”²⁸

<p>Plaintiffs</p>
<p>Plain and ordinary meaning. No construction is necessary. Alternatively, “a component that allows material to be combined with compounds for determining the presence of one or more polynucleotides.”</p>
<p>Defendants</p>
<p>The second processing region is a portion of the microfluidic network that receives the eluate solution containing polynucleotides and places the eluate solution in contact with PCR reagents to form a PCR-ready solution.</p>
<p>Court</p>
<p>No construction is necessary.</p>

As with “first processing region,” the portions of Defendants’ construction that simply repeat claim language are redundant and unnecessary.

The parties’ fundamental dispute is whether the “second processing region” is required to be part of the microfluidic network or may simply be part of the *system* of which the microfluidic network is a part. The claim language makes clear that the “*first* processing region is within a microfluidic network in the system.” ’663 patent at 33:32-34. By contrast, the claim language refers to the “*second* processing region” as merely being “in the system.” *Id.* at 33:52-

²⁸ This term appears in claims 1-49 of the ’663 patent and claims 1-39 of the ’788 patent. These two patents share a common specification.

53. This distinction provides persuasive evidence that the patentee did not intend to require the second processing region to be part of the microfluidic network. (*See* D.I. 146 at 116)

The specification language is consistent with this understanding, as it describes the possibility of removing solution from the first processing region via a “syringe or automated sampling device.” *See, e.g.*, ’663 patent at 15:26-33. Several dependent claims similarly contemplate removal of solution with “an automated sampling device,” “a syringe,” or “a pipette.” ’788 patent at 35:1-6, 36:46-48. That the patentee contemplated methods of transfer taking place *outside* of the microfluidic network suggests the patentee did not intend to foreclose a system in which a second processing region could be *separate* from the microfluidic network. (*See* D.I. 146 at 120)

To the extent Defendants seek to draw support for their proposal from the specification’s second embodiment, their approach fails. As already explained, the claims are not limited to the second embodiment. *See generally Hill-Rom Servs.*, 755 F.3d at 1372.

Given this resolution of the parties’ disputes, the Court concludes the meaning of “second processing region” is clear and the term does not require construction.

III. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.